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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/085,840 | 02/27/2002 | Velayudhan Sahadevan | | 1770 |
| 7590 | 10/03/2003 | | EXAMINER | |
| Dr. V. Sahadevan Dag Hammarskjold Cancer Treatment Center 155 Dry Hill Road Beckley, WV 25801 | | | AZPURU, CARLOS A | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1615 | |
| DATE MAILED: 10/03/2003 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------------|-----------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/085,840 | SAHADEVAN, VELAYUDHAN |
| | Examiner Carlos A. Azpuru | Art Unit 1615 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on ____.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-34 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
 5) Claim(s) 18-24 and 26-32 is/are allowed.
 6) Claim(s) 1-17,25,33 and 34 is/are rejected.
 7) Claim(s) ____ is/are objected to.
 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 11) The proposed drawing correction filed on ____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) The translation of the foreign language provisional application has been received.
 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

| | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of the information disclosure statement filed 02/27/03.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 34 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention:

The invention provides for various types of implants for delivery of an antiestrogen and various steroid hormones which are administered subcutaneously, intramuscularly, or directly into breast tissue.

(2) The state of the prior art:

The prior art discloses the use of oral and/or systemic treatment of breast cancer.

(3) The relative skill of those in the art

The relative skill of those in the art is high since the dosages for each form of drug delivery differs and must be carefully monitored for toxicity.

(4) The predictability or unpredictability of the art

The unpredictability of hormone therapy is very high. While hormone therapy seems to be effective, each patient needs to be evaluated individually due to various possible side effects,

Art Unit: 1615

adverse reactions, and new information on susceptibility to other forms of cancer (such as ovarian or uterine).

(5) The breadth of the claims

The claims are fairly specific as to the placement and use of the implants.

(6) The amount of direction or guidance presented

The specification is directed to implants for the treatment of breast cancer when administered subcutaneously, intramuscularly, or within breast tissue. There is no direction as to prophylactic effect. The article "Broader than the Disclosure in Chemical Cases," 31 J.P.O.S. 5, by Samuel S. Levin covers this subject in detail. A disclosure should contain representative examples which provide reasonable assurance to one skilled in the art that the compounds fall within the scope of a claim will possess the alleged activity. See *In re Riat et al.* (CCPA 1964) 327 F2d 685, 140 USPQ 471; *In re Barr et al.* (CCPA 1971) 444 F 2d 349, 151 USPQ 724.

(7) The presence or absence of working examples

The working examples of the instant application are all directed to the manufacture and use of the instant drug delivery implants in the treatment of breast cancer.

(8) The quantity of experimentation necessary

Since the efficacy of a prophylactic treatment must be evaluated individually, and over a long period of time, one of ordinary skill in the art would be burdened with undue "painstaking experimentation study" to determine whether the claimed treatment method would also function as a means of prophylaxis of breast cancer.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17 , 25 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 11 and 14 are indefinite in the use of the word "improved" and "longer". Both are relative terms without quantifiable measurements against which they can be measured. As such, they do not particularly point out the invention. Applicant is requested to make appropriate corrections.

Claims 6 and 7 are indefinite in that it is not particularly pointed out as to which drug compositions "are made as separate or in combination thereof." Exactly what is separated, and what is combined? Clarification is requested.

Claim 25 is indefinite in that it refers to prostatic implantation and not breast implantation. Clarification is requested.

Claim 33 uses the relative terms "lesser-cost" and "more convenient" which again can not be quantified, and therefore does not particularly point out the invention. Appropriate action is requested.

Claims 18-24, 26-32 are in condition for allowance.

Gupta is cited for disclosure of an implant capable of delivering various steroid hormones through subcutaneous administration.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is 703/308-0237. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

ca



CARLOS A. AZPURU
PRIMARY EXAMINER
GROUP 1500